Knowledge Acquisition Session Report
Clinical Research Nurse Manager – Baylor U. Medical Center

Session Date: 5/30/01 **Session Time:** 1:30 – 2:45 p.m.

Session Topic: Clinical Research Nurse Tasks

Knowledge Analyst: Bill McCurry

Session Location: Baylor University Medical Center, Dallas, Texas

Type of Session:

_X_ Interview	__ Task Analysis	__ Scenario Analysis
__ Concept Analysis	__ Observation	__ Structured Interview
__ Other:		

Documentation: KA Session Report

General Topic Area

Clinical Research Nurse Tasks

Session Goals:

- Document the typical clinical research nurse tasks
- Identify people and organizations with whom the clinical research nurse frequently interacts
- Identify areas in the clinical research nurse's workflow that could benefit from the insertion of information technology

Report Summary

This report details the major tasks of a Clinical Research Nurse (CRN) as described by Ms. Aimee Lanier, RN, of Baylor University Medical Center. A CRN may be able to share the some tasks with others if a skilled nursing staff and/or a Research Supervisor is available. However, many research departments have only a single CRN who must do everything. Typical CRN tasks fall into the following areas: work with patients, manage data collection, reporting, manage budgets and contracts, and recruit studies from sponsors. CRNs spend a significant amount of time and effort locating and organizing clinical trial source documents (the document on which the data was first recorded). CRNs would benefit from technologies that help feed clinical trial information directly into electronic source documents.

Domain Expert Background

Ms. Aimee Lanier, RN, serves as the Research Supervisor of the Baylor University Medical Center Institute of Transplantation Sciences in Dallas, Texas. In this capacity she supervises a staff of about 15 Clinical Research Nurses. Ms. Lanier has also worked as a Clinical Research Nurse in oncology

clinical trials. Based on her experiences, she stated that the Clinical Research nurse tasks in the transplantation sciences field are not very different from those in oncology.

Clinical Research Nurse Tasks

Clinical Research Nurses (CRNs) may perform a wide variety of tasks to support clinical trials. These tasks range from hands-on work with clinical trial patients to working with clinical trial budgets and contracts. Figure 1 shows a high level view of Clinical Research Nurse tasks.

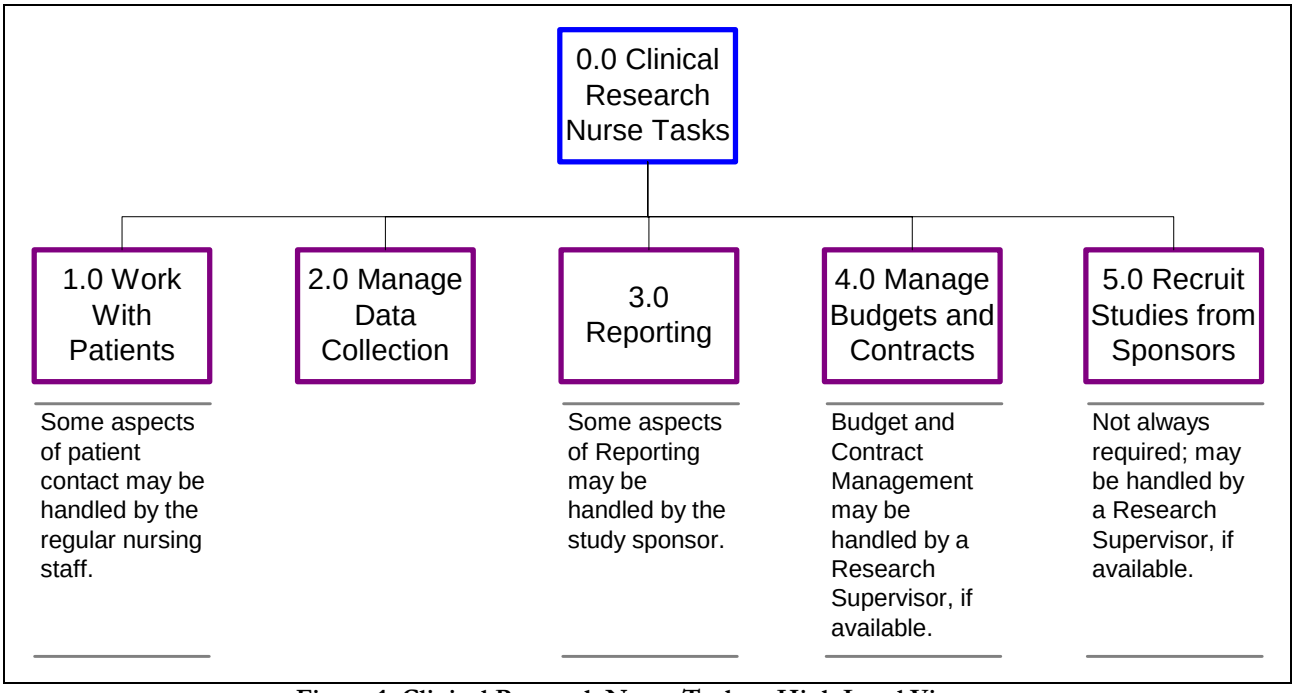

Figure 1: Clinical Research Nurse Tasks – High Level View

In some situations, a Clinical Research Nurse must perform all of the required tasks. In other situations other individuals handle some of the tasks, or the tasks may not be required. Several factors determine whether or not the Clinical Research Nurse will perform a particular task. These factors include:

- Availability of a Research Supervisor
- Complexity of the clinical trial protocol
- Extent to which the protocol exceeds the normal standard of care
- Experience of the regular nursing staff
- Willingness of the regular nursing staff to work with the clinical trial requirements
- Organization sponsoring the clinical trial
- Need to actively recruit clinical trials from sponsors

Work With Patients

In some clinical trial situations Clinical Research Nurses interact with patients frequently. In other situations CRNs rarely see patients. If the clinical trial does not require procedures or data collection outside the facility's normal standard of care, then the facility's regular nursing staff can handle the work with patients. There is no reason for the CRN to handle those tasks. However, most clinical trials require some work above the facility's normal standard of care.

Even when clinical trials demand extra work, the regular nursing staff may handle much of the work with patients. This requires that the regular nursing staff be experienced, accustomed to clinical trial procedures, and willing to collect clinical trial data. The CRN prepares worksheets, flowsheets and orders to help caregivers follow the clinical trial protocol. These tools are invaluable when the regular nursing staff is handling most of the patient contact in a clinical trial.

Sometimes the regular nursing staff is unable or unwilling to handle the additional work required for the clinical trial. In those cases the CRN must handle the patient contact to ensure that the clinical trial protocol is correctly followed.

Figure 2 shows the patient contact tasks for a Clinical Research Nurse.

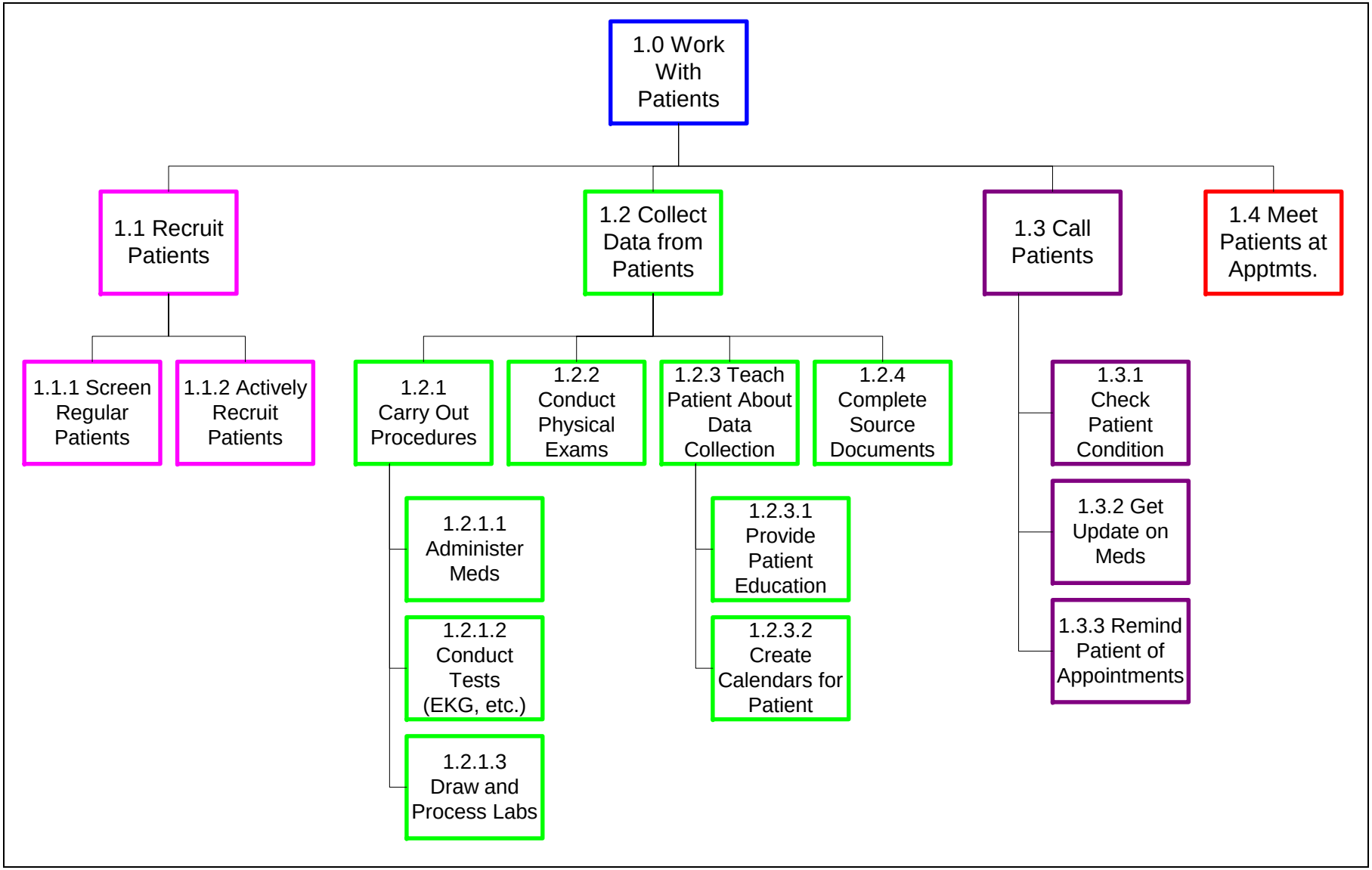

Figure 2: Clinical Research Nurse Tasks - Work With Patients

Recruit Patients

A clinical trial's authors set goals for the number of patients to participate in the trial. Patients are recruited onto clinical trials in two ways:

- *Screen Regular Patients:* Patients referred to the facility for treatment in the normal course of operations are evaluated for clinical trial eligibility. This may require capture of additional patient history or additional testing to evaluate eligibility.
- *Actively Recruit Patients:* If an insufficient number of patients are available through normal admissions and referrals, the CRN may be required to actively recruit patients for the clinical trial. The CRN accomplishes this by reviewing facility records and contacting prospective clinical trial participants individually.

Collect Data From Patients

A wide variety of data are collected from patients in the course of a clinical trial. Patient data collection tasks break down in the following ways:

- *Carry Out Procedures:* CRNs (or regular nursing staff) carry out medical procedures as required by the protocol. Some of the procedures are carried out specifically to collect data for the clinical trial. Commonly required procedures include:
    - Administer Medications
    - Conduct Tests (such as electrocardiogram)
    - Draw and process samples for lab tests
- *Conduct Physical Exams:* Patient information is collected during physical exams, via direct observation of the patient and also via the patient's comments and responses to questions.
- *Teach Patient About Data Collection:* Some aspects of data collection must be completed by the patient himself. This includes recording self-administered medications and keeping diaries. The CRN or nursing staff must:
    - Educate the patient about data collection for the clinical trial
    - Create calendars and other aids to help the patient effectively collect clinical trial data
- *Complete Source Documents:* A clinical trial source document is the place in which data were initially recorded upon collection. No matter where the data are subsequently copied, the source document remains the authoritative description of the data. CRNs and regular nurses must take great care to correctly complete source documents during data collection.

Call Patients

During the course of a clinical trial CRNs (or regular nursing staff) must call patients frequently to check on the patients and give them reminders. Some of the specific tasks that involve calling patients include:

- *Check Patient Condition:* Between visits to the facility CRNs may call the patient to check on progress, ensure that no adverse events are occurring, and reassure the patient.
- *Get Update on Medications:* The CRN may call the patient to find out whether the patient is adhering to the medication schedule and whether any medication-related problems seem to be occurring.

- *Remind Patient of Appointments:* The CRN will sometimes call the patient to remind him of upcoming appointments for treatment or evaluation.

Meet Patients at Appointments

Patients are scheduled for appointments with many different clinicians during the course of a clinical trial. The CRN may sometimes meet a patient for one of these appointments to reassure and assist the patient.

Manage Data Collection

Clinical Research Nurses spend a significant amount of time on data collection management tasks during a clinical trial. These tasks must be handled by the CRN rather than by the regular nursing staff. Figure 3 depicts the Clinical Research Nurse data collection management tasks.

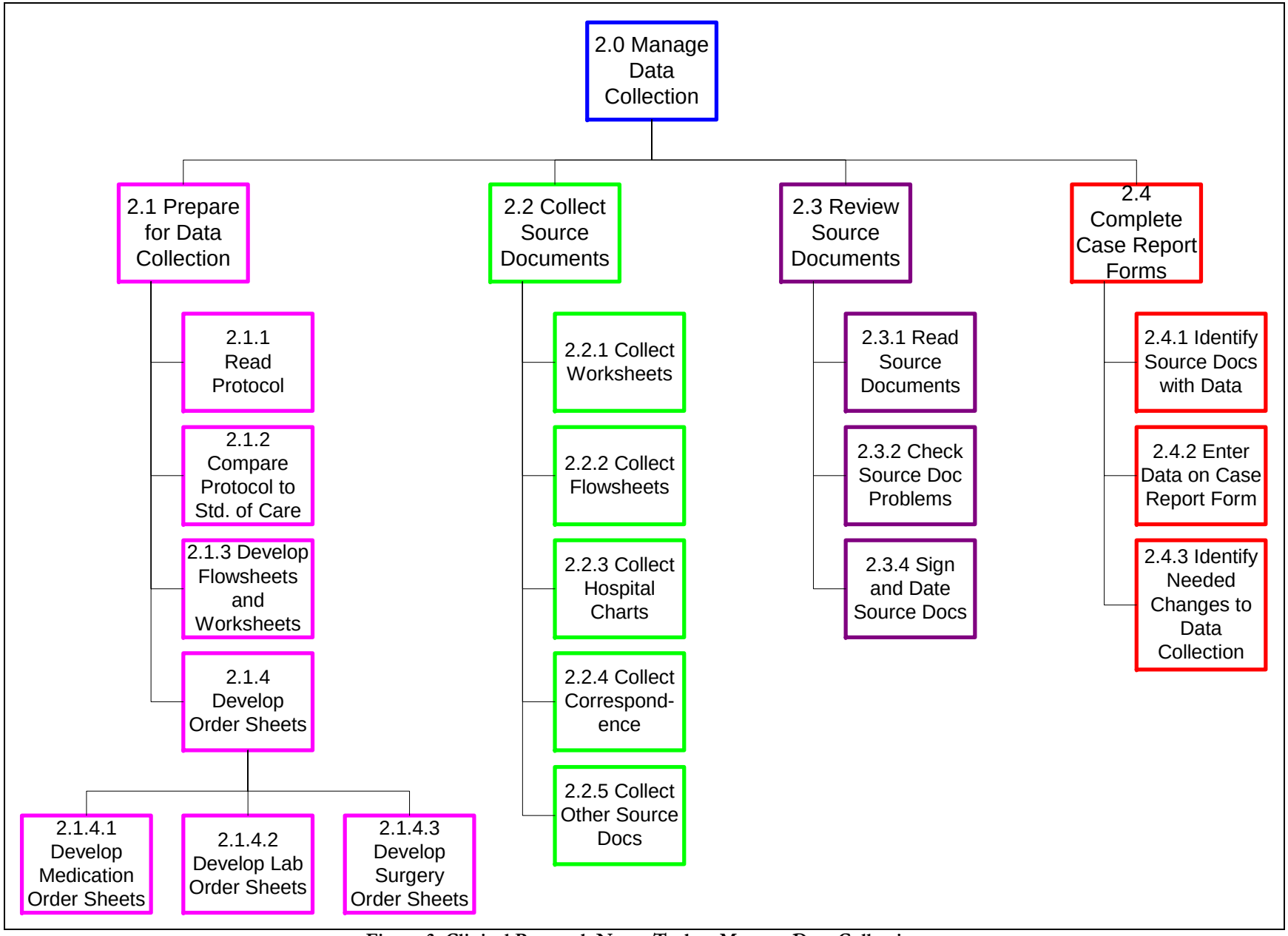

Figure 3: Clinical Research Nurse Tasks - Manage Data Collection

Prepare for Data Collection

The CRN must understand the data required by the protocol and the case report forms and plan for data collection. The tasks involved in preparing for data collection include:

- *Read the Protocol:* The CRN must thoroughly examine the protocol document and its associated case report forms.
- *Compare Protocol to Standard of Care:* Each facility provides a standard of care and collects data associated with that standard. The CRN must evaluate what data collection beyond the standard of care will be required for the clinical trial.
- *Develop Flowsheets and Worksheets:* The CRN creates paper-based aids to help everyone involved in the clinical trial collect the required data at the correct time and in the correct manner.
- *Develop Order Sheets:* The CRN writes order sheets detailing any procedures required by the clinical trial that exceed the facility's standard of care. Order sheets may be developed specifically for:
    - Administering medications
    - Conducting lab tests and other tests
    - Capturing data during surgery

Collect Source Documents

CRNs must collect the various source documents that have been used to record the collected clinical trial data. These source documents may be in the possession of many different individuals who have been involved in the clinical trial, including the patient and physicians outside the facility. Types of source documents that must be collected include:

- *Worksheets*
- *Flowsheets*
- *Hospital Charts*
- *Correspondence*
- *Other Source Documents*

The source document is the place in which data were initially recorded upon collection. In many cases this is a document designed for the purpose (e.g., a worksheet). In other cases data may be collected in informal settings. For example, the patient may report symptoms of an adverse event during a phone call. In those cases, the source document could be a page from a notepad, an envelope, or even a napkin. This fact causes the task of collecting source documents to be a time-consuming process for CRNs.

Review Source Documents

The CRN must review the collected source documents, investigate any apparent problems, and verify accuracy. The source document review tasks include:

- *Read Source Documents:* The CRN reads and evaluates the content of each source document, noting any potential inconsistencies or problems.

- *Check Source Document Problems:* The CRN investigates and resolves any potential inconsistencies or problems with any source documents. This may involve contacting the individual who completed the source document in question.
- *Sign and Date Source Documents:* The CRN signs and dates each source document once satisfied that the document is complete and accurate.

Complete Case Report Forms

Each clinical trial protocol includes case report forms for data collection. A set of case report forms must be completed for each patient participating in a clinical trial. The CRN case report form completion tasks include:

- *Identify Source Documents With Data:* The CRN must identify the source document containing the data for each data element required on a case report form. This ensures that the data recorded on the case report forms are as accurate as possible. Ms. Lanier described the process of matching source documents to case report forms as something like assembling a jigsaw puzzle. She also pointed out that the practice of checking source documents sometimes prevents the submission of incorrect data.
- *Enter Data on Case Report Form:* Once all of the necessary source documents are identified, the CRN completes the case report form by hand.
- *Identify Needed Changes to Data Collection:* While completing case report forms the CRN may identify changes that are needed to improve data collection and management for the clinical trial. For example, additional order sheets or worksheets may be designed because of problems identified as case report forms were completed.

Reporting

Each clinical trial requires reporting to various entities. All facilities have a local Institutional Review Board (IRB) that monitors and approves clinical trial activity. The Clinical Research Nurse must provide clinical trial reports to the facility's IRB on a regular basis.

Third parties such as pharmaceutical companies and government agencies provide funds for many clinical trials. In such cases, the facility must provide clinical trial reports to the sponsoring organization. The sponsoring organization then handles any regulatory reporting required by the Food and Drug Administration (FDA).

The facility may fund some clinical trials itself. In these instances the facility need not provide reports to a sponsor, but must handle the regulatory reporting to the FDA. Figure 4 shows the Clinical Research Nurse reporting tasks.

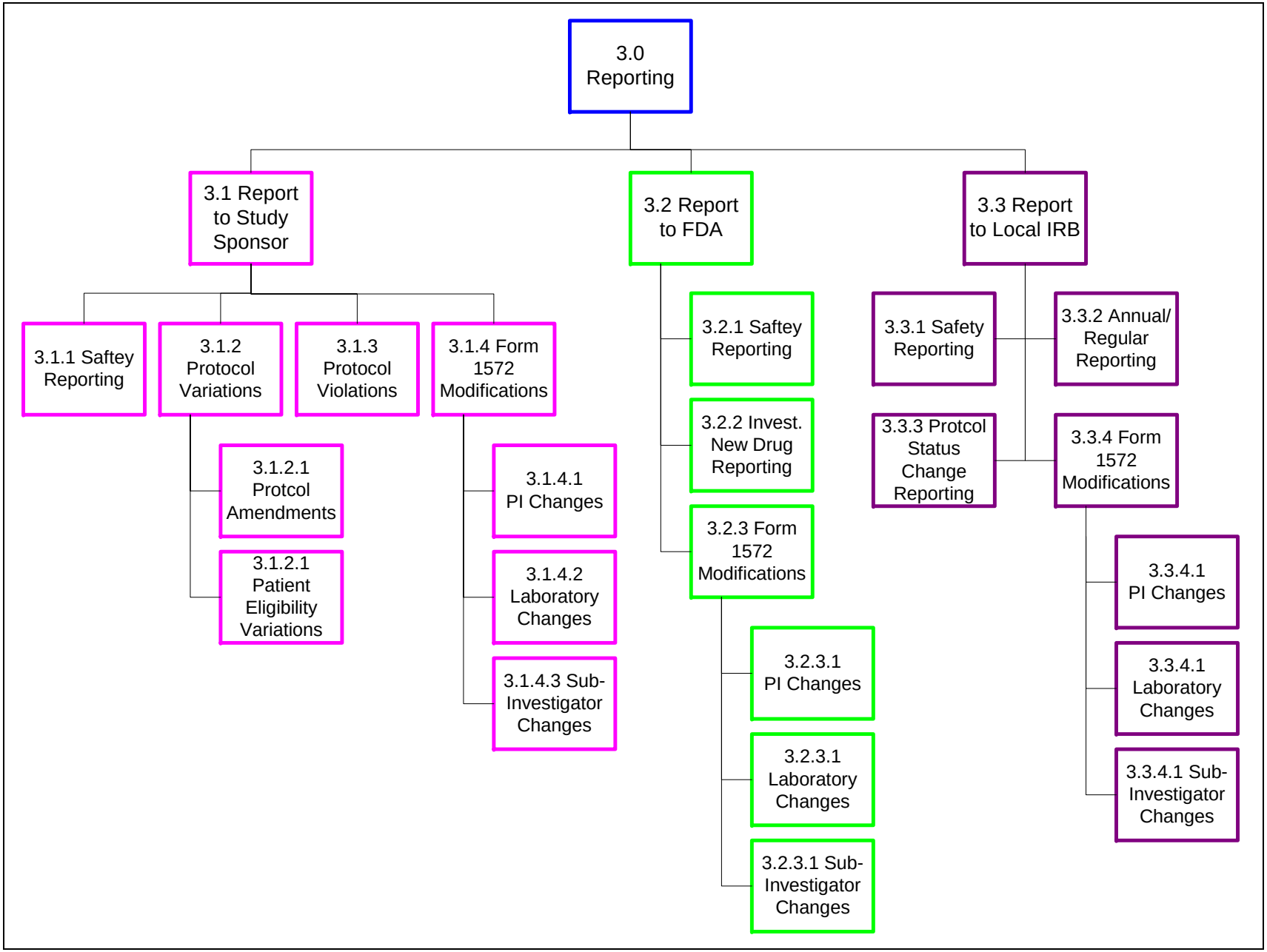

Figure 4: Clinical Research Nurse Tasks - Reporting

Report to Study Sponsor

The CRN must produce a variety of reports for the study sponsor, if the clinical trial has been sponsored by a government agency, pharmaceutical company or other third party. In some cases the CRN develops the reports, while in other cases the CRN works with the principal investigator or other facility personnel to develop the reports. The CRN sponsor reporting tasks include:

- *Safety Reporting:* The facility must report any adverse events experienced by a patient on the clinical trial. Serious adverse events must be reported within a short period of time after their occurrence.
- *Protocol Variations:* The facility must communicate with the sponsor about variations to the protocol. Types of protocol variations include:
    - Protocol Amendments: The sponsor must approve any changes to the overall clinical trial protocol. Such changes are approved as protocol amendments. The facility must report back to the sponsor on amendment-related changes that have been put in place.
    - Patient Eligibility Variations: Sometimes a patient is eligible for a clinical trial in all respects except for one lab value slightly out of norm. The facility may contact the sponsor to report this and request permission to enroll the patient on the clinical trial.
- *Protocol Violations:* The facility must notify the sponsor if treatments, evaluations or other events fail to follow the instructions in the clinical trial protocol.
- *Form 1572 Modifications:* Form 1572 is used to indicate the investigators and labs that are authorized to work on a clinical trial. The facility must notify the sponsor whenever a Form 1572 is modified. Specific modifications that require notification include:
    - Principal Investigator Changes
    - Laboratory Changes
    - Sub-Investigator Changes

Report to FDA

When the facility itself funds the clinical trial and no third party sponsor is involved, the facility must provide all the regulatory reporting to the FDA. If a third party is sponsoring the trial, then the sponsor handles the FDA reporting. CRN tasks for FDA reporting include:

- *Safety Reporting:* The FDA requires that all adverse events be reported within a certain period of time after occurrence. Serious adverse events must be reported more quickly than other adverse events.
- *Investigational New Drug Reporting:* If the clinical trial involves an investigational new drug, the FDA requires additional reporting related to the drug, its toxicity, and its effects.
- *Form 1572 Modifications:* The FDA must be notified whenever a Form 1572 is modified. Specific modifications that require notification include:
    - Principal Investigator Changes
    - Laboratory Changes
    - Sub-Investigator Changes

Report to Local Institutional Review Board

All clinical trials require reporting to the local Institutional Review Board (IRB). Clinical Research Nurse Tasks related to IRB reporting include:

- *Safety Reporting:* The facility must report adverse events and serious adverse events to the IRB.
- *Annual/Regular Reporting:* The IRB requires regular reports on the status of each clinical trial. Status information includes patient accruals, adverse events, and amendments. Such reports are typically required annually. However, the IRB may decide that the risk involved with a particular clinical warrants more frequent reporting.
- *Protocol Status Change Reporting:* The IRB must receive a report whenever a clinical trial changes status. Status changes include initiations, amendments, being placed on hold, closure, and completion. Status change reports must be made immediately and are outside of regular reporting to the IRB.
- *Form 1572 Modifications:* The IRB must be notified whenever a Form 1572 is modified. Specific modifications that require notification include:
    - Principal Investigator Changes
    - Laboratory Changes
    - Sub-Investigator Changes

Manage Budgets and Contracts

A research facility must develop and manage a budget for each clinical trial at that facility. The facility also signs a contract with the sponsor organization of each clinical trial. The Research Supervisor, if available, will handle budget and contract tasks. However, if a Research Supervisor is not available then the Clinical Research Nurse must handle budget and contract tasks. Figure 5 shows the Clinical Research Nurse budget and contract management tasks.

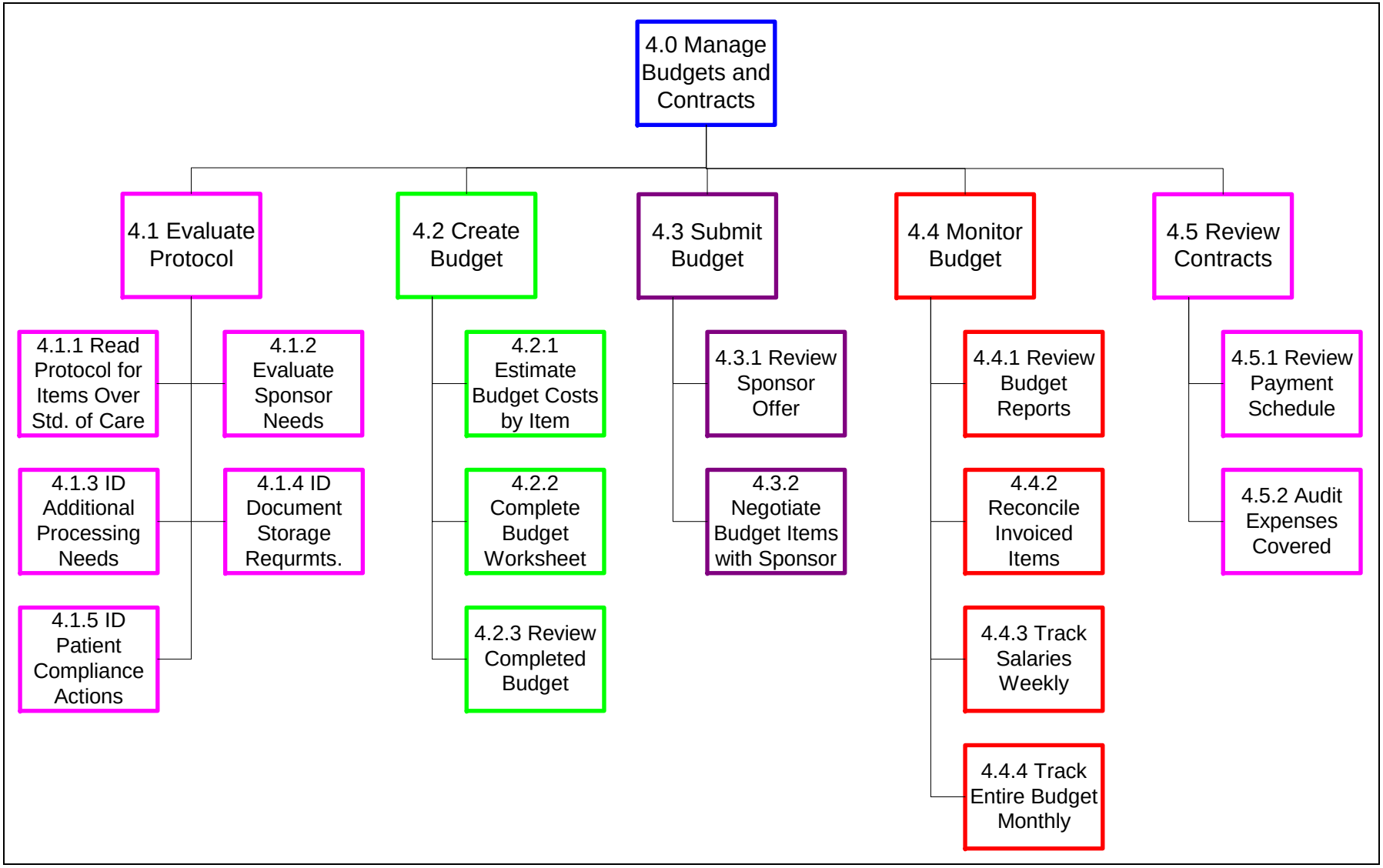

Figure 5: Clinical Research Nurse Tasks - Manage Contracts and Budgets

Evaluate Protocol

The Clinical Research Nurse (or Research Supervisor) must evaluate the clinical trial protocol to identify all requirements that will impact the clinical trial budget. The CRN tasks involved in evaluating the protocol for budgetary purposes include:

- *Read the Protocol for Items Over the Standard of Care:* Each facility provides a standard of care for its patients. Clinical trial protocols may require procedures and data collection above the normal standard of care. The CRN must note all such items for possible inclusion in the clinical trial budget.
- *Evaluate Sponsor Needs:* The clinical trial's sponsor may have specific reporting needs, auditing needs, or other requirements beyond the items specified in the protocol. The CRN must identify and evaluate those items for budgetary purposes.
- *Identify Additional Processing Needs:* The CRN must identify any clinical trial requirements that involve additional processing. For example, the facility may be require to ship samples to the sponsor, to fax case report forms each Friday, or to use special equipment such as a cold centrifuge.
- *Identify Document Storage Requirements:* The CRN must estimate how many documents will be generated from the clinical trial and determine how long the facility will be required to keep those documents.
- *Identify Patient Compliance Actions:* The CRN must determine actions that must be taken at facility expense to ensure that patients meet the study requirements. For example, the patient may be required to travel to remote labs for some tests.

Create Budget

Once the protocol and circumstances of the clinical trial have been thoroughly evaluated, the CRN (or Research Supervisor) must develop a budget for the clinical trial. CRN budget creation tasks include:

- *Estimate Budget Costs by Item:* In some cases the CRN will simply develop a lump sum budget estimate based on a protocol evaluation and past experience. However, the CRN more frequently estimates the cost of each item identified during the protocol evaluation. The largest expense in any clinical trial budget will be salary dollars for facility personnel.
- *Complete Budget Worksheet:* When the budget is developed by item, the CRN must complete a spreadsheet for the clinical trial budget, providing all of the items identified and an estimated cost for each.
- *Review Completed Budget:* The CRN reviews the completed budget for accuracy, completeness and reasonableness.

Submit Budget

When satisfied with the clinical trial budget, the CRN (or Research Supervisor) forwards it to the facility Financial Office. The Financial Office then submits the budget to the

sponsoring organization. The sponsor will return an offer that must be reviewed and sometimes negotiated. CRN tasks involving budget submission include:

- *Review Sponsor Offer:* The CRN must carefully review the offer that the sponsor provided in response to the submitted budget. The CRN identifies items in the offer that might prevent the facility from successfully and economically completing the clinical trial.
- *Negotiate Budget Items With Sponsor:* The CRN participates in negotiations with the sponsor over budget items that seem to have inadequate compensation.

Monitor Budget

Once the clinical trial budget has been approved, the CRN (or Research Supervisor) must monitor actual expenses against the budget. If actual expenses seem to be exceeding the budget, the CRN must take action to correct the situation. CRN budget monitoring tasks include:

- *Review Budget Reports:* The CRN must review monthly budget reports for accuracy and completeness.
- *Reconcile Invoiced Items:* The CRN must reconcile invoices for materials and services charged to the clinical trial.
- *Track Salaries Weekly:* Since salary dollars represent the largest expense for the clinical trial, the CRN tracks salary expenditures for the trial weekly.
- *Track Entire Budget Monthly:* The CRN tracks and evaluates the entire budget for the clinical trial once each month.

Review Contracts

Contract review occurs at the same time as the budgetary review of the sponsor's offer. The CRN (or Research Supervisor) help the Financial Office review the proposed contract. The CRN provides the expertise needed to evaluate whether clinical aspects of the contract are adequate for the facility.

- *Review Payment Schedule:* The CRN reviews the contract's payment schedule to ensure that sponsor payments occur in time to cover the procedures and activities required for the clinical trial.
- *Audit Expenses Covered:* The CRN audits the expenses covered by the contract to ensure that all expenses required for the clinical trial are covered.

Recruit Studies from Sponsors

Some facilities actively recruit clinical trials from sponsor organization. The Research Supervisor, if available, will handle this type of task. If there is no Research Supervisor, then the Clinical Research Nurse must identify upcoming clinical trials, contact the sponsoring organizations, and discuss the facility's possible participation in those trials.

Clinical Research Nurse Interactions with People and Organizations

Individuals and organizations with whom the Clinical Research Nurse frequently interacts include:

- Research Supervisor
- Regular nursing staff
- Clinical Research Assistant
- Patient
- Investigator/physician
- Laboratory personnel
- Sponsor representative
- Institutional Review Board representative
- FDA representative
- Finance Office personnel

Interaction with Investigators

The Clinical Research Nurse and the Investigator work as a team on the clinical trial. They communicate at least daily and usually more frequently. The CRN makes rounds with the physician and sees the patient with the physician. When face-to-face communication is not possible, the CRN and Investigator stay in touch by way of notes, emails and letters.

Application of Technology to Clinical Research Nurse Tasks

Ms. Lanier identified two areas in which technology might be applied to assist Clinical Research Nurses.

Automated Source Documentation

One of the most difficult and time-consuming aspects of collecting source documents is finding documentation completed outside the facility. For example, the source documents for results from remote laboratories can be difficult to collect. CRNs would benefit from a system that allows laboratories to upload their results data directly to an electronic case report form. In such a system, the case report form itself would become the source document. This would greatly reduce the need to locate, review, organize and store source documents.

Dictation to Electronic Documents

Clinical Research Nurses and other clinicians would benefit from a system that allowed them to dictate notes directly into electronic documents. The notes might be stored directly in electronic case report forms, or they might be saved as electronic source

documents. In either case, the system would simplify the task of locating, organizing, and storing source documents for the CRN's notes and observations.